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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/113,924	07/09/1998	DAVID R. BRIGSTOCK	08766/003002	8612

28213 7590 11/23/2009

DLA PIPER LLP (US)
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/113,924	BRIGSTOCK ET AL.	
	Examiner	Art Unit	
	Lorraine Spector	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8, 9, and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8, 9, and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/18/09 has been entered.

Claims 8, 9, and 13-17 are pending and under consideration. Any rejection not repeated in this Office Action is withdrawn.

It is noted that SEQ ID NO: 2 corresponds to residues 248-259 of SEQ ID NO: 2 of U.S. Patent No. 5,408,040 with the exception that Xaa in the instant sequence is actually a string of five residues in the patented sequence.

It is further noted that SEQ ID NO: 5, which has not been previously examined, differs from SEQ ID NO: 1 by having a cysteine residue where the X is in SEQ ID NO:1, and in lacking the two C-terminal residues of SEQ ID NO: 1. SEQ ID NO: 5 differs from SEQ ID NO: 2 in being one residue longer at the amino and carboxyl termini, and having a cysteine residue at the position where SEQ ID NO: 2 has an X.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8, 9, and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipate by U.S. Patent No. 5,795,862 (Frank et al.).

Frank et al. disclose a SEQ ID NO: 31, which is a 6/7 match to SEQ ID NO: 2, varying only at the c-terminus of SEQ ID NO: 2. The alignment of the two sequences is shown in the appendix to this Office Action. SEQ ID NO: 31 has a total length of 25 residues and the match is at residues 3-9, near the N-terminus, and therefore expected to be available as an antigen. Further, the sequence is not shared with VEGF. The same residues are present in SEQ ID NO: 1 and 5 of the instant application. The property of not binding to PDGF would be inherent to the shared epitope. The protein of SEQ ID NO: 31 is specifically claimed. The fragment is disclosed as being from Ectoparasite saliva proteins. Antibodies are disclosed at column 4, lines 16-18. At column 45, beginning at line 28, it is stated that antibodies to the proteins may be monoclonal or polyclonal.

Claim 9 introduces the limitation that the antibody binds specifically to an amino acid sequence a set forth in SEQ ID NO: 2. Given the similarity to the fragment of Frank et al., it would be expected that Frank's antibodies would meet these limitations. However, the Examiner, lacking laboratory facilities, is unable to determine such unequivocally. Since the Office does not have the facilities for examining and comparing applicants' antibodies with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Applicants arguments, filed 9/18/09, have been fully considered but are not deemed persuasive. At page 7, applicants have argued that epitopes may be continuous or discontinuous, and have cited a paper by Larsen et al., whch they have not made of record, to support their argument. This argument has been fully considered but is not deemed persuasive because applicants have made no connection between the teachings of Larsen et al. and the *particular* fragment in question. Given the small length of the fragments to which the antibodies are

required to bind, and the even smaller length of Frank's fragment, the possibility of secondary or tertiary structure obscuring the epitope is small. Further, applicants have presented no fact or evidence that antibodies to the small fragments in question would be expected to be different; see the reference to *in re Best* and *Ex parte Gray*, above.

At the paragraph bridging pages 7-8, applicants argue that the source of Frank's protein is different from the source of the HBGF fragments in question, that six amino acids represents the lower limit for an epitope, and that it would not be *predicted* that the sequence in question would form an epitope. This argument has been fully considered but is not deemed persuasive because applicants have not provided documentation of their allegation. Thus, the Examiner cannot assess the asserted fact. Further, the Examiner has visited the site in question; it is not clear what tools were used by applicants, and how. Accordingly, applicants argument constitutes neither fact nor evidence. Also, it is known in the art that five amino acids are sufficient to form an epitope; see Reddehase et al., made of record herein.

Finally, at the bottom of page 8, applicant argues that "Moreover, Frank does not disclose any particular isolated antibodies to Ectoparasite saliva proteins, any particular isolated antibodies to the fragment of sequence SEQ ID NO: 31, or any particular isolated antibodies that recognize the 6 common amino acids ENIKKG. What Frank describes are antibodies that are capable of selectively binding to an Ectoparasite saliva product (Col 4, lines 16-18). Applicant contends that the antibodies that are capable of selectively binding to an Ectoparasite saliva protein would not be ones which also specifically bind to a HBGF protein (as required in the present invention). The antibodies described in Frank therefore do not anticipate the presently claimed antibodies." This argument has been fully considered but is not deemed persuasive because it is not necessary that Frank have actually made the antibodies. As was found in *In re Graves*, 36 USPQ 2d1697 at 1701, "A reference anticipates a claim if it discloses the claimed invention "such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention". Such is the case here. Frank does not have to have actually made the antibodies, but rather merely has to describe how to make them in a manner that would enable a skilled artisan to do so. With regard to the source of the proteins, this is completely irrelevant. An amino acid sequence does not bear an

identification tag disclosing where it was obtained, nor would the tag alter the sequence itself. All that is relevant here is the commonality of the two sequences.

Accordingly, the rejection is maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday from 8:00 A.M. to 4:30 P.M., and Tuesday, Thursday and Friday, 8:00 A.M. to 2:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Gary Nickol, at telephone number 571-272-0835.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed

copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
/Lorraine Spector/
Primary Examiner
Art Unit 1647

Appendix- Sequence Alignments

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RESULT 5
US-08-487-001A-31
; Sequence 31, Application US/08487001A
; Patent No. 5795862
;  GENERAL INFORMATION:
;     APPLICANT:  FRANK, GLENN R.
;     APPLICANT:  HUNTER, SHIRLEY WU
;     APPLICANT:  WALLENFELS, LYNDA
;     TITLE OF INVENTION:  NOVEL ECTOPARASITE SALIVA
;     TITLE OF INVENTION:  PROTEINS AND APPARATUS TO COLLECT SUCH PROTEINS
;     NUMBER OF SEQUENCES:  54
;     CORRESPONDENCE ADDRESS:
;       ADDRESSEE:  Sheridan Ross & McIntosh
;       STREET:  1700 Lincoln Street, Suite 3500
;       CITY:  Denver
;       STATE:  Colorado
;       COUNTRY:  U.S.A.
;       ZIP:  80203
;     COMPUTER READABLE FORM:
;       MEDIUM TYPE:  Floppy disk
;       COMPUTER:  IBM PC compatible
;       OPERATING SYSTEM:  PC-DOS/MS-DOS
;       SOFTWARE:  PatentIn Release #1.0, Version #1.25
;     CURRENT APPLICATION DATA:
;       APPLICATION NUMBER:  US/08/487,001A
;       FILING DATE:  07-JUN-1995
;       CLASSIFICATION:  424
;     ATTORNEY/AGENT INFORMATION:
;       NAME:  Verser, Carol Talkington
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;      REGISTRATION NUMBER:  37,459
;      REFERENCE/DOCKET NUMBER:  2618-17-C2
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (303) 863-9700
;      TELEFAX:  (303) 863-0223
;  INFORMATION FOR SEQ ID NO:  31:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  25 amino acids
;      TYPE:  amino acid
;      TOPOLOGY:  linear
;    MOLECULE TYPE:  protein
US-08-487-001A-31

  Query Match             58.2%;  Score 32;  DB 1;  Length 25;
  Best Local Similarity   85.7%;  Pred. No. 88;
  Matches    6;  Conservative    1;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ENIKKGK 7
              ||||||:
Db          3 ENIKKGE 9
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